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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,079	02/16/2000	Joni Kristin Doherty	49321-1A	5713

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Davis Wright Tremaine LLP
2600 Century Square
1501 Fourth Avenue
Seattle, WA 98101-1688

EXAMINER
HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
1642	18

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/506,079	DOHERTY ET AL.	
	Examin r	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE f this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 8-10 and 18-20, drawn to polypeptides and pharmaceutical compositions, the polypeptide binds to the extracellular domain of HER-2, classified in class 530, subclass 300, 350 or 387.1.

II. Claims 4-7 and 11-13, drawn to polynucleotides and host cells, the polynucleotide encodes for a polypeptide that binds to the extracellular domain of HER-2, classified in class 536, subclass 23.5.

III. Claims 14-17 and 21-23, drawn to methods for treatment of a solid tumor, classified in class 424, subclass 130.1.

IV. Claims 24-26, drawn to methods for determining the prognosis of cancer treatment comprising measuring the amount of p68HER-2, classified in class 435, subclass 7.1.

V. Claims 27-33, drawn to assay for cancer treatment, prognosis or diagnosis, comprising the detection of an ECDIIIa variant, classified in class 435, subclass 4, 6 or 7.1.

VI. Claims 34-37, drawn to antibodies and kits, the antibodies specific for an ECDIIIa variant, classified in class 530, subclass 387.1.

2. The inventions are distinct, each from the other, for the following reasons:

Groups I, II and VI are drawn to separate and distinct products. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive

groups that are directed to different products, restriction is deemed to be proper because these products constitute distinct inventions for the following reasons: The proteins of group I, the polynucleotides of group II, and the antibodies of group VI are chemically distinct products unrelated in chemical structure and separately classified, having separate fields of search. The proteins of group I have no relationship with the polynucleotides or antibodies of either group II or group V. The function and existence of DNA, protein or antibody is independent of the function and existence of the other. The products of groups I, and II can be independently synthesized by chemical means. An antibody is encoded by an entirely different DNA than that which encodes the protein to which it binds, and the primary sequence of the antibody is entirely different from the primary sequence of the protein to which it binds. Each of the products has separate, unrelated uses and is not disclosed as being capable of use together with any other products. Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

Groups III, IV, and V are drawn to separate and distinct processes. Group III is drawn to methods for treatment of a solid tumor comprising administering an agent that binds the extracelluar domain of HER-2. Group IV is drawn to methods for determining the prognosis of tumor treatment comprising measuring the levels of p68HER-2 levels. Group V is drawn to methods for cancer treatment, prognosis or diagnosis comprising determining whether an ECDIIIa variant sequence is present in a bodily fluid. Thus, groups III and IV are separate and distinct methods because they comprise different method steps, use different products and result in different endpoints. Group III is drawn to methods of treatment, which comprise different method steps and use different products than the methods of either of the in vitro methods of

Group III or Group IV. Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of group I may be used in in vitro methods of purification of HER-2, which are methods that are materially different from the methods of treatment of group III.

Inventions VI and V are related as product and process of use, to the extent that the methods of group V rely on immunological methods of detection. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of group V may be performed by the detection of polynucleotide sequences, which are methods that do not use the product of group VI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even thought the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
September 29, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600